

Remarks

Claims 1, 6, 9, 27, 29, 31, and 34-40 are pending. With these amendments, claim 33 is canceled and the dependencies of claims 34 and 35 are amended. Claim 1 is amended to recite a method of treating pancreatic in a mammalian subject afflicted with pancreatitis, which has been previously presented in prior Replies. Support for this amendment can also be found throughout the specification, for example, at paragraphs [0002], [0021], [0046], [0047] and [0048], and in the claims as originally filed. No new matter is added by these amendments and entry thereof is respectfully requested.

Rejections under 35 USC §103

Claims 1, 6, 9, 27, 29, 31, and 33-40 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Young in view of Iovanna, Valter, Jorgensen, and Haddad.

Applicants arguments with respect to this rejection and its inappropriate reliance on anticipatory inherency were explained in the Replies filed 6/30/09, 2/17/10, and 11/19/10. These arguments are specifically relied on and the issue reserved for appeal. With respect to the rejection mailed 1/31/11 and the reply to Applicant's arguments submitted 11/19/10, the cited references provide no disclosure regarding the treatment of pancreatitis by administering amylin or an amylin analog, and nor does any cited reference or combination provide a motivation to treat pancreatitis with amylin or an amylin analog. Further, the cited references fail to disclose or suggest the biological effects of amylin and amylin agonists on pancreatic enzymes. On the other hand, Applicants describe for the first time the unexpected benefit of simultaneously reducing pancreatic enzyme levels and relieving pain with the use of any amylin and amylin agonists (see, for example, paragraph [0048]).

The logic of the rejection appears to be that the motivation is to treat the pain associated with pancreatitis, and by so doing one is inherently treating the pancreatitis. But this position has no legal foundation because inherency is a concept in anticipation, and there is no legal doctrine of obviousness by inherency. Furthermore, as explained in detail in the Reply filed 6/30/09, the requirements even of the inappropriately applied anticipatory inherency doctrine are not met in

the present case. Therefore, the rejection has no legal basis and reconsideration is respectfully requested.

As explained by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007), the appropriate analysis is to apply the *Graham* factors, which are the controlling inquiries in any obviousness analysis. Thus the scope and content of the prior art must be considered, the differences between the claimed invention and the prior art ascertained, and resolving the level of the person of ordinary skill in the art. When such analysis is performed here it is seen that no cited reference or any combination of them teaches or suggests that amylin or an amylin analog may be useful in the treatment of pancreatitis.

Additionally, the present claim recites that the method is for treating pancreatitis in a mammalian subject afflicted with pancreatitis. Thus, the claim requires that the methods be performed on a subject actually afflicted with pancreatitis. The Federal Circuit has held that where a claim was drawn to treating or preventing a specific disease and where the claim required that the active ingredient be administered “to a human in need thereof,” that the need must be recognized and appreciated for the claim to be infringed. *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 68 USPQ2d 1154 (Fed. Cir. 2003). In the present case the claims are drawn to treating pancreatitis in a subject that is afflicted with pancreatitis. And in like manner these claims require that the need be recognized and appreciated and that the subject be afflicted with pancreatitis, and that the amylin or amylin agonist be administered for the purpose of treating the pancreatitis. *Jansen* (“The preamble is ... a statement of the intentional purpose for which the method must be performed”). Since none of the cited references, nor any combination thereof, teach or suggest such a treatment, the claims are not rendered obvious by the cited references.

Conclusion

An early and favorable consideration and allowance of Claims 1, 6, 9, 27, 29, 31, and 34-40 is respectfully requested.

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Respectfully submitted,



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